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10/056,998	01/25/2002	Mark P. Ohan	270/275US	3516

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EXAMINER
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GHALI, ISIS A D

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 10/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/056,998

Applicant(s)

OHAN ET AL.

Examiner

Isis Ghali

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07/30/2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

The receipt is acknowledged of applicants' amendment and request for extension of time, both filed 07/30/2004.

Claims 2, 10-14 have been canceled.

**Claims 1, 3-9 are included in the prosecution.**

#### ***Claim Rejections - 35 USC § 112***

1. Claims 3 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are confusing as they recite "collagen mixture" that reads as a mixture of different types of collagen. Recourse to the specification revealed that the collagen mixture is collagen and appropriate solvent, page 9, line 14 of the present specification. Appropriate correction is requested.

Applicants have failed to traverse the rejection and the response is considered to be acquiescence to the position taken by the examiner. The rejection is therefore repeated for reasons of record. See MPEP 37 CFR 1.111 (b).

**The following new ground of rejections are necessitated by applicant amendment:**

***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1, 3, 4, 6, 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,292,362 ('362).

US '362 discloses a composition in the form of liquid or gel comprising collagen and sugar selected from oligosaccharide such as fructose, or polysaccharide; or any

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other component as would be obvious to one skilled in the art (col.4, lines 53-68; col.5, lines 9-43). The composition is irradiated by ultraviolet irradiation (col.5, lines 56-60).

The composition is prepared by mixing the components, agitating the mixture to form solution or gel, then exposure to the irradiation at use (col.13, lines 16-24). The collagen is in the form of solution or hydrated components, and that reads on the collagen mixture because applicants disclosed the collagen mixture as collagen and solvent, page 9, line 14 (col.4, lines 29-30; col.13, lines 1-5).

The reference however does not teach the specific sugars claimed in claims 1 and 6. However, the art recognized composition comprising sugar and collagen as a strong water-tight flexible wound sealing, as desired by applicants to have a durable material obtained by adding sugar that provides strength and integrity to the collagen, see the present disclosure page 8, lines 21-22 and page 11, lines 1-2. On the other hand, applicants in their disclosure page 10, lines 1-3 disclosed the fructose and sucrose as equivalent to any other sugar claimed in claims 1 and 6 and the reference also disclosed the equivalency between oligosaccharide and polysaccharide in the wound sealing composition.

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a composition comprising collagen and sugar as disclosed by the reference, and select the sugar according to the properties and intended use of the composition, with reasonable expectation of having a composition comprising collagen and other oligosaccharide or other polysaccharide that can be used as a strong water-tight flexible wound sealing, as desired by applicants.

5. Claims 1, 3, 4, 6, 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,632,773 ('773).

US '773 discloses a composition in the form of gel comprising collagen and sugar such as sucrose (col.6, lines 48-51; col.7, lines 21-30). The composition is irradiated by gamma or ultraviolet irradiation (col.6, lines 60-66). Example I disclosed the method of mixing the components and exposing the mixture to irradiation. The collagen is in from of solution or gel, and that reads on the collagen mixture because applicants disclosed the collagen mixture as collagen and solvent, page 9, line 14 (col.6, lines 49-57).

The reference however does not teach the specific sugars claimed in claims 1 and 6. However, the art recognized composition comprising sugar and collagen as a composition with enhanced biostability, as desired by applicants to have a durable material obtained by adding sugar that provides strength and integrity to the collagen, see the present disclosure page 8, lines 21-22 and page 11, lines 1-2. On the other hand, applicants in their disclosure page 10, lines 1-3 disclosed the fructose and sucrose as equivalent to any other sugar claimed in claims 1 and 6.

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a composition comprising collagen and sugar as disclosed by the reference, and select the sugar according to the properties and intended use of the composition, with reasonable expectation of having a composition comprising collagen and other sucrose that has enhanced biostability, as desired by applicants.

**The following rejections were discussed in details in the previous office action, and maintained for reasons of record:**

6. Claims 5 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of US '362 or US '773, each standing by itself or in view of US 5,716,633 ('633).

The teachings of US '362 and US '773 are discussed above. The references, however, do not teach the gamma radiation is subsequent to UV radiation.

It is within the skill in the art to select the polymerization technique depending on the desired character of the collagen based on the intended use because the nature of collagen is altered by the way of cross-linking, such as strength and color etc. Applicants did not show superior or unexpected results from the exposure of the composition to gamma radiation subsequent to UV radiation. Thus, exposure of the composition to gamma radiation subsequent to UV radiation does not render the claims patentable, absent evidence to the contrary.

US '633 teaches collagen hydrogel for promoting epithelial cell growth during healing process (abstract; col.4, lines 58-59; col.11, lines 25-29). The collagen hydrogel is exposed to gamma radiation and then placed under UV light (col.13, lines 54-59).

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide composition comprising irradiated sugar and collagen as disclosed by both of US '362 and US '773, and perform both gamma and UV irradiation as disclosed by US '633, motivated by the teaching of US '633 that the collagen hydrogel produced cross-linked by irradiation promotes epithelial cell growth during

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healing process, with reasonable expectation of having an irradiated composition comprising sugar and collagen mixture that is used successfully in wound healing compositions.

### ***Response to Arguments***

7. Applicant's arguments filed 07/30/2004 have been fully considered but they are not persuasive.

Applicants traverse the rejection of the claims over US '362 and US '773 by arguing that the references do not teach the specific sugars as claimed.

Applicants traverse the rejection of the claims over US '633 by arguing that reference teaches UV radiation subsequent to gamma irradiation, and not the reverse.

Applicants find no suggestion or motivation to combine the cited reference together and there is no reasonable expectation of success of applying the irradiation process (UV irradiation subsequent to gamma irradiation) of the '633 Patent to the compositions of the '773 Patent or the '362 Patent.

In response to the above applicants' argument, the examiner position is that the art recognized composition comprising collagen and sugar as a wound healing material. Thus, the claimed invention as a whole is obvious over the prior art. Further, applicants themselves admit the equivalency of different sugars, page 10, lines 1-2 of the disclosure. The disclosed examples and preferred embodiment do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. *In re Susi*, 440

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F.2d 442, 169 USPQ 423 (CCPA 1971). The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain. *In re Heck*, 699 F.2d 1331, 1332—33, 216 USPQ 1038, 1039 (Fed. Cir 1983). A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill in the art, including nonpreferred embodiments. In considering the disclosure of the reference, it is proper to take into account not only the specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom. *In re Preda*, 401 F.2d 825, 826, 159 USPQ 342, 344 (CCPA 1968).

Regarding applicants' argument that US '633 by arguing that reference teaches UV radiation subsequent to gamma irradiation, the examiner position is that reversing the order of the prior art process and selection of any order of performing process steps is *prima facie* obvious, absence of new or unexpected results. Applicants disclosed that the composition can be exposed to UV irradiation, or gamma irradiation, or both.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, one having

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ordinary skill in the art would have been motivated by the teaching of US '633 that the collagen hydrogel exposed to both UV radiation and gamma irradiation promotes epithelial cell growth during healing process.

The rational to modify or to combine the prior art does not have to be expressly stated in the prior art; the rational may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art. The reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve different problem. It is not necessary that the prior art suggest the combination or modification to achieve the same advantage or result discovered by applicant. *In re Linter*, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972).

It is well established that the claims are given the broadest interpretation during examination. A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the claims would have been obvious within the meaning of 35 U.S.C. 103 (a).

***Conclusion***

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis Ghali  
Examiner  
Art Unit 1615

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